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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------------------|
| 10/612,754 | 07/01/2003 | Thomas W. Mower | 14564.37.1 | 5557 |
| 7590 | 10/11/2006 | | | EXAMINER SHEIKH, HUMERA N |
| JOHN C. STRINGHAM WORKMAN, NYDEGGER & SEELEY 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111 | | | ART UNIT 1615 | PAPER NUMBER |
| DATE MAILED: 10/11/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/612,754 | MOWER ET AL. |
| | Examiner | Art Unit |
| | Humera N. Sheikh | 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 July 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) 13-19, 21 and 22 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12, 20 and 23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

*Humera N. Sheikh
Humera N. SHEIKH
Primary Examiner
7C-1600*

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 11/15/2005

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Arguments/Remarks, both filed 07/21/06 and the Information Disclosure Statement (IDS) filed 11/15/2005 is acknowledged.

Applicant's election without traverse of Group I (Claims 1-12, 20 & 23) in the reply filed on 07/21/2006 is acknowledged.

Claims 13-19, 21 and 22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/21/2006.

Claims 1-23 are pending in this action. Claims 13-19, 21 & 22 have been withdrawn. Claims 1-12, 20 and 23 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su *et al.* (U.S. Patent Publication No. 2002/0068102 A1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

The instant invention is drawn to a dietary supplement comprising: noni fruit; Luo Han Guo; and water.

The instant invention is also drawn to a method of improving the taste and odor of noni-based dietary supplements, comprising: providing a noni fruit product; mixing with the noni fruit product; powdered Luo Han Guo; and liquid Luo Han Guo; whereby the powdered Luo Han Guo provides a masking effect to cover the unpleasant tastes and/or odors of the noni and the liquid Luo Han Guo acts as a sweetener for the dietary supplement.

The instant invention is also drawn to a method of improving the taste and odor of a noni-based dietary supplement, while simultaneously prolonging the shelf life thereof, comprising: providing a noni-based fruit product; mixing with the noni fruit product; powdered Luo Han Guo; liquid Luo Han Guo; raspberry fruit concentrate; and blueberry fruit concentrate.

Su et al. ('102) teach a dietary supplement to reduce cellular damage within the human body, whereby the dietary supplement includes reconstituted *Morinda citrifolia* (noni) fruit juice. The dietary supplement may also include other natural juices, such as natural blueberry juice concentrate and/or another natural juice concentrate. In one implementation, where liquid is extracted from the fruit of *Morinda citrifolia* to create the dietary supplement, it is referred to as 'Tahitian Noni' (see Abstract); (page 1, ¶ 13); (pg. 3, ¶ 28).

Su et al. teach that when the *Morinda citrifolia* fruit is ripe or overripe, the fruit provides a foul odor and/or taste (pg. 2, ¶ 25).

To prepare the supplement, *Morinda citrifolia* juice and puree are typically blended in a homogeneous blend, after which they are mixed with other ingredients, such as flavorings, sweeteners, nutritional ingredients, botanicals, extracts, and/or colorings. For example, flavorings may include artificial and/or natural flavor or ingredients that contribute to palatability. Sweeteners taught include natural sugars, artificial and high-intensity sweeteners. Specific sweeteners taught include natural sugars derived from corn, sucralose, stevia, saccharin, etc. (pg. 3, ¶ 35).

Consumption amounts of the dietary supplement may include more than one ounce per day or less than one ounce per day (pg. 1, ¶ 15 – pg. 2 ¶ 15).

With regard to the instant ‘method of improving taste and odor’ of noni based dietary supplements, it is the position of the Examiner that the instant method would be considered *prima facie* obvious based on the disclosure and teachings of Su *et al.*, as Su et al. teach a noni-based (*Morinda citrifolia*) dietary supplement that comprises at least one of flavorings and sweeteners (see for instance, Claim 13).

While Su *et al.* do not explicitly teach the instant amounts of noni fruit, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the Examiner’s position that Applicants have not demonstrated any surprising or unexpected results that accrue from the claimed amounts of noni fruit. The prior art clearly recognizes and teaches formulations based on noni fruit, particularly, *Morinda citrifolia*, used in dietary supplement formulations.

Su *et al.* as discussed above, teach that *Morinda citrifolia* provides a foul odor and/or taste when ripe or overripe. Su *et al.* also teach that flavoring agents, sweetening agents and the like are added in the supplement to contribute to palatability.

Su *et al.* do not teach inclusion of Luo Han Guo and raspberry concentrate.

Fischer et al. (‘965) teach beverage and sweetening compositions comprising Luo Han Guo. The Luo Han Guo is provided in serum, puree or juice form and is used as a sweetening ingredient in place of sugar (see reference column 1, line 25 – col. 2, line 46). The use of Luo

Han Guo allows for good tasting, storage-stable beverages and can be used in beverages, such as fruit juices and fruit juice-containing beverages (col. 2, lines 29-35). Luo Han Guo provides for a reduced calorie, flavoring system that has acceptable mouth feel and taste characteristics, particularly, a beverage without off-flavors (col. 2, lines 47-62); (col. 12, lines 27-30).

The Luo Han Guo-containing sweet juices can be concentrated but are mostly used as a single strength juice or as a dry powder (col. 4, lines 20-40).

Luo Han Guo is preferably present at an amount of from 0.25 to 10% (col. 10, lines 27-36). See also Examples on cols. 16-19. This amount is an overlapping amount, which reads on the instantly claimed amount of from about 0.1% to about 3%.

Flavoring agents that can be used include raspberry, blueberry and the like (col. 4, lines 4-19); (col. 11, lines 44-59). The flavoring agents are provided in amounts of from 0.01% to 3% by weight (col. 11, lines 26-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry flavorants as taught by Fischer *et al.* within the dietary supplement of Su *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Fischer *et al.* teach a high-intensity sweetener, Luo Han Guo and teach that it is used as a sweetening agent, useful for providing good taste, with acceptable mouth feel and taste characteristics and also teach that additional flavorants and juices include raspberry to make low calorie beverages. The expected result would be an improved, palatable, reduced-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the

art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

The teachings of Su *et al.* are discussed above. Su *et al.* teach that *Morinda citrifolia* provides a foul odor and/or taste when ripe or overripe. Su *et al.* also teach that flavoring agents, sweetening agents and the like are added in the supplement to contribute to palatability.

Su *et al.* do not teach inclusion of Luo Han Guo and raspberry concentrate.

Downton *et al.* ('755) teach a sweet juice composition comprising Luo Han Guo. The sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage (see reference column 2, lines 1-26); (col. 3, lines 3-15) and Examples at cols. 12-15. An objective is to also produce a fruit juice, which is lower in sugar and calories by blending the very sweet (Luo Han Guo) juice with other fruit juices (col. 2, lines 27-30). Other suitable fruit juices disclosed include raspberry fruit juices (col. 10, lines 30-50). The sweet juice has a pH of less than about 4.5 (claim 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry juices as taught by Downton *et al.*

within the dietary supplement of Su *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Downton *et al.* teach a natural sweetener, Luo Han Guo, whereby the sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage and also teach that additional fruit juices, such as raspberry are included in the Luo Han Guo juice to make low calorie (lower sugar) beverages. The expected result would be an enhanced, palatable, low-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

Claims 1-12, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yegorova (U.S. Patent No. 6,387,370 B1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

The instant invention is drawn to a dietary supplement comprising: noni fruit; Luo Han Guo; and water.

The instant invention is also drawn to a method of improving the taste and odor of noni-based dietary supplements, comprising: providing a noni fruit product; mixing with the noni fruit product; powdered Luo Han Guo; and liquid Luo Han Guo; whereby the powdered Luo Han Guo provides a masking effect to cover the unpleasant tastes and/or odors of the noni and the liquid Luo Han Guo acts as a sweetener for the dietary supplement.

The instant invention is also drawn to a method of improving the taste and odor of a noni-based dietary supplement, while simultaneously prolonging the shelf life thereof, comprising: providing a noni-based fruit product; mixing with the noni fruit product; powdered Luo Han Guo; liquid Luo Han Guo; raspberry fruit concentrate; and blueberry fruit concentrate.

Yegorova ('370) teaches dietary supplement compositions that include extracts of *Morinda citrifolia*, also called Noni juice, and blueberry extracts (see Abstract); (col. 5, lines 22-26); (col. 6, line 66 – col. 7, line 10).

The preparations may be in solid form, such as a capsule, powder or granule, or a tablet form. Alternatively, the compositions may be dispersed into a suitable liquid. The composition may also be administered orally, preferably two to three times daily (col. 5, lines 14-20); (col. 11, lines 46-56).

The composition may comprise *Morinda citrifolia* extract in an amount ranging from about 50 mg to about 150 mg and blueberry extract in an amount ranging from about 25 mg to about 75 mg (col. 4, lines 21-34); (col. 7, lines 35-42); (col. 8, lines 62-66).

In a preferred embodiment, the compositions may comprise 100 mg of *Morinda citrifolia* extract obtained by extracting the *Morinda citrifolia* fruit with water (col. 8, lines 1-7).

According to Yegorova, compositions comprising blueberry extract, have been used to retard the aging process, as blueberries comprise large amounts of antioxidants. Blueberries rank in the top five of an antioxidant assay called ORAC (oxygen radical absorbance capacity) (col. 7, lines 7-10); (col. 8, lines 31-66).

Example 1 at columns 12-13 demonstrates a composition that includes *Morinda citrifolia* (100 mg) and blueberry extract (50 mg).

While Yegorova does not explicitly teach the instantly claimed amounts of noni fruit, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the Examiner’s position that Applicants have not demonstrated any surprising or unexpected results that accrue from the claimed amounts of noni fruit. The prior art clearly recognizes and teaches dietary formulations based on noni fruit, particularly, *Morinda citrifolia* in combination with antioxidant-containing blueberry extract.

Yegorova does not teach inclusion of Luo Han Guo and raspberry concentrate.

Fischer et al. (‘965) teach beverage and sweetening compositions comprising Luo Han Guo. The Luo Han Guo is provided in serum, puree or juice form and is used as a sweetening ingredient in place of sugar (see reference column 1, line 25 – col. 2, line 46). The use of Luo Han Guo allows for good tasting, storage-stable beverages and can be used in beverages, such as

fruit juices and fruit juice-containing beverages (col. 2, lines 29-35). Luo Han Guo provides for a reduced calorie, flavoring system that has acceptable mouth feel and taste characteristics, particularly, a beverage without off-flavors (col. 2, lines 47-62); (col. 12, lines 27-30).

The Luo Han Guo-containing sweet juices can be concentrated but are mostly used as a single strength juice or as a dry powder (col. 4, lines 20-40).

Luo Han Guo is preferably present at an amount of from 0.25 to 10% (col. 10, lines 27-36). See also Examples on cols. 16-19. This amount is an overlapping amount, which reads on the instantly claimed amount of from about 0.1% to about 3%.

Flavoring agents that can be used include raspberry, blueberry and the like (col. 4, lines 4-19); (col. 11, lines 44-59). The flavoring agents are provided in amounts of from 0.01% to 3% by weight (col. 11, lines 26-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry flavorants as taught by Fischer *et al.* within the dietary supplement of Yegorova. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Fischer *et al.* teach a high-intensity sweetener, Luo Han Guo and teach that it is used as a sweetening agent, useful for providing good taste, with acceptable mouth feel and taste characteristics and also teach that additional flavorants and juices include raspberry to make low calorie beverages. The expected result would be an improved, palatable, reduced-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or

manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

The teachings of Yegorova are delineated above.

Yegorova do not teach Luo Han Guo and raspberry concentrate.

Downton et al. ('755) teach a sweet juice composition comprising Luo Han Guo. The sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage (see reference column 2, lines 1-26); (col. 3, lines 3-15) and Examples at cols. 12-15. An objective is to also produce a fruit juice, which is lower in sugar and calories by blending the very sweet (Luo Han Guo) juice with other fruit juices (col. 2, lines 27-30). Other suitable fruit juices disclosed include raspberry fruit juices (col. 10, lines 30-50). The sweet juice has a pH of less than about 4.5 (claim 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry juices as taught by Downton *et al.* within the dietary supplement of Yegorova. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Downton *et al.* teach a natural sweetener, Luo Han Guo, whereby the sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform

substantial quantities of off-flavors during storage and also teach that additional fruit juices, such as raspberry are included in the Luo Han Guo juice to make low calorie (lower sugar) beverages. The expected result would be an low-calorie dietary supplement composition that offers improved taste and flavoring.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

Pertinent Art

Prior art not relied upon but deemed relevant by Examiner:

- *Xiong et al.* (U.S. Patent No. 6,299,925 B1)

Xiong et al. teach a green tea extract formulation comprising Noni fruit, obtained from *Morinda citrifolia* plant. The formulation also contains fruit extracts, such as blueberry and raspberry extract (see Abstract; col. 6, lines 61-65; col. 8, Example VII; and Claim 23).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Primary Examiner

Humera N. Sheikh
7C-1600

Art Unit 1615

September 28, 2006

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